K 122181

Visgeneer Inc.
No. 188 Sec.3, Gongdao 5th Rd., Hsinchu City 30069, Taiwan
Tel: +886-3-5160111 Fax: +886-3-5160161

Section V 510(K) Summary

This Summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of (Per 21 CFR 807.92)

Submitter's Name

Visgeneer Inc.
No.188, Sec.3, Gongdao 5th Rd., Hsinchu City 30069, Taiwan
Tel: +886-5160111 Fax: +886-5160161
Contact Person: Jack Yang
Date prepared: June 14th, 2013

AUG 15 2013

Name of Device

Trade Name: *eBchek* Blood Glucose Monitoring System
Common Name: Blood Glucose Monitoring System

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1345	Class II	CGA, glucose oxidase, glucose	Clinical Chemistry (75)
21 CFR § 862.1345	Class II	NBW, system, test, blood glucose, over the counter	Clinical Chemistry (75)
21 CFR § 862.1660	Class I, reserved	JJX, single (specified) analyte controls (assayed and unassayed)	Clinical Chemistry (75)

Predicate Device:

Visgeneer Inc., eBsensor Blood Glucose Monitoring System (K062555)

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Description of Device:

Based on an electrochemical biosensor technology and the principle of capillary action, eB*chek* Blood Glucose Monitoring System only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed on the meter. This system contains some speaking functions, but is not intended for use by the visually impaired.

The e*Bchek* Blood Glucose Monitoring System consists of the e*Bchek* Meter, e*Bchek* test strips with instruction, lancing device, lancets, code card, two AAA Batteries, users manual, carrying case. e*B-series* control solutions (previously cleared in K062555 as eBsensor control solution) with two different glucose concentration ranges (Level 1 and Level 2) are available but sold separately.

Intended Use:

The eB*chek* Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The eB*chek* Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The eB*chek* Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The eBchek Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus or for neonatal use. The eBchek Glucose Meter contains some speaking functions, but is not intended for use by the visually impaired.

e*Bchek* Blood Glucose Test Strips are for use with the eB*chek* Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

eB-*series* Control Solutions are for use with the eB*chek* Blood Glucose Meter and eB*chek* Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

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Comparison to Predicate Device

Similarities		
Item	**Device**	**Predicate Device(K062555)**
Device name	eB*chek*	eB*sensor* (Model : eB-G)
Test Principle	Electrochemical biosensor with carbon electrodes	Same
Specimen Type	capillary whole blood	Same
Measurement unit	mg/dL or mmol/L	Same
Enzyme	Glucose oxidase	Same
Control Solution	eB-series control solution (contains D-glucose, two different concentrations are used, ie. Level 1:100 mg/dL and Level 2:300 mg/dL)	Same composition and mixture, but under labeling of eBsensor control solution
A Code card	Code card(for each batch of test strip)	Same
Strip Dimension	7.9mm*32mm	Same
Battery Power	Two 1.5 V AAA batteries	Same
Operating Temp.	4 to 42 ℃	Same
Operating Humidity	10 to 85%	Same
Meter Storage	0~50℃	Same

Differences		
Item	**Device**	**Predicate Device**
Intended use	Single patient	Single patient and Healthcare Professionals
Sample Volume	0.5 uL	2.5 uL
Measuring Time	5 sec	10 sec
HCT Range	20~60%	30 ~ 55 %
Detecting Range	20 ~ 600 mg/dL (1.1~33.3mmol/L)	30 ~ 600 mg/dL (1.6~33.3mmol/L)
Slot location	Bottom	Top

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Meter Check	Autocheck	Check Strip
Average Display	7, 14 and 28 days	-
Memory Storage	450 blood glucose result	70 blood glucose results
Alarm Function	Alarm clock	-
Talking Function	English/Chinese	-
Meter Dimension Length X Width X Height	95 mm X 55 mm X 18.5 mm	87 mm X 60 mm X 21 mm
Meter Weight	85 g	75 g

The Subject device is different from the predicate device in the following aspects:
*Meter: ergonomic/physical design, hardware, slight modification of firmware and electronics to include talking function.
*Strips: Modifications in GOD enzyme dosage and the reaction chamber on the eBchek test strips was made to fill blood samples according to the specified volume.
*Control Solution: There are no changes to the ingredients of Normal and High Control Solutions from the predicate. Proposed labeling is changed from previously cleared k number K062555, eBsensor control solution to eB-series control solution.
There have been no changes to the operating principle or general scientific technology from the predicate.

Performance Studies

Study is based on ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
Performance on the eBchek Blood Glucose Monitoring System demonstrated that the device meets the requirements for its intended use. The data demonstrates that the device is substantially equivalent to the predicate and raises no safety or effectiveness issues.

Conclusion

The modification of e*Bchek* Blood Glucose Monitoring System does not affect the safety and effectiveness of the device. The submitted information in this premarket notification supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

Visgeneer, Inc.
C/O Jack Yang
No. 188, Sec. 3, Gongdao 5th Rd.
Hsinchu City 30069, Taiwan

Re: K122181
Trade/Device Name: eBchek Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: July 31, 2013
Received: August 8, 2013

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122181

Device Name: *eBchek Blood Glucose Monitoring System*

Indications for Use:

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Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k122181